



HALO Frequently Asked Questions:

Why is screening for breast cancer so important?

1 in 8 women will develop breast cancer in their lifetime, but to date, it's been very difficult to identify who is at risk. Traditional methods of breast cancer screening have limiting factors. Women under the age of 40 are not usually getting regular mammograms. For women over 40, mammograms often do not detect abnormal changes up to 8 years after changes have begun to take place. Mammograms are also not as effective in women with dense breasts. HALO is a screening tool that can help identify women at greatest risk, earlier, allowing for earlier intervention and increasing chances for survival.

What is the difference between a screening test and a diagnostic test?

A screening test allows physicians to group asymptomatic (no symptoms) patients in different categories from low risk to high risk. A diagnostic test confirms whether or not symptomatic (with symptoms) patients actually have a disease. HALO is a screening test and works much like a cholesterol screen for potential cardiovascular disease. Just because you have high cholesterol doesn't mean you have heart disease. Similarly, just because you have atypia does not mean you have breast cancer.

Does HALO replace mammograms?

No, HALO is a complement to mammograms. Mammograms look for lesions (cancer) and are most effective as women age. HALO is looking for abnormal cells, years before they might turn into a lesion, and the test is effective in women as young as 25. If you already have a growth in your milk ducts when you first have a HALO test, it is possible that the affected duct could be blocked so that HALO could not collect a fluid sample. This is why it's important to continue with routine mammograms and breast exams.

What about family history?

Those who have a first degree relative with breast cancer are 2 to 3 times more likely to develop the disease. Those who have atypia are 4 to 5 times more likely to develop breast cancer. Those who have both a family history and atypia may be up to 18 times more likely to develop breast cancer. Screening for atypia with HALO will help you and your doctor identify cellular changes, closely monitor them, and develop an optimal care path.

How does the HALO Breast Pap Test work?

HALO combines warmth, massage and suction to bring nipple aspirate fluid (NAF) to the surface. NAF is found in the milk ducts where 95% of all breast cancers originate. The entire cycle is five minutes and is easily incorporated into your well-woman visit. If you produce fluid, the sample is then sent to the lab and analyzed for cellular changes.



Who should have HALO and how often?

This is an annual test for women over 25. Women over 55 are known to decrease their production of NAF and mammograms become more effective at this age.

Is the procedure painful?

Most women find this test easy to tolerate. In a clinical study with 500 women, 88% said they would recommend it to their friends. On a 1-10 scale, the average discomfort rating for the HALO was about a 4 while those same women rated their mammogram an 8.

How many women produce fluid?

About half of all women will produce fluid. Not producing fluid with the HALO test is considered a normal result, meaning you are at normal risk, not elevated risk for developing breast cancer.

What if I don't produce fluid?

If you don't produce fluid, this is considered a normal result. You are at normal risk, not elevated risk for developing breast cancer.

If I have atypia, does it mean I have breast cancer?

No. It simply means that you are at higher risk than someone without atypia. In fact, only about 1% to 2% of women screened have atypia and often times atypia corrects itself, especially if lifestyle changes are made such as diet, exercise and reducing alcohol intake.

What do I do if I get an abnormal result?

There are specific carepaths for your consideration. In general, if you have an abnormal result you will likely be referred to a breast center. The breast specialist has several options in 3 broad categories:

- Full risk assessment questionnaire and counseling about preventive measures
- Diagnostic mammogram, Ultrasound, or MRI
- More aggressive options to include medication such as tamoxifen; procedures like ductal lavage, ductoscopy, or ductal incisions, etc.

What happens if I do not produce Nipple Aspirate Fluid (NAF)?

Approximately half of women do not produce NAF. This is considered a normal result. Clinical data has shown that women who do not produce fluid are at the lowest relative risk. Women who do not produce NAF one year may produce NAF the next year therefore, the HALO Breast Pap Test should be conducted annually.



How long does it take to get results?

Typically it takes three to five days. Your doctor's office will call you to discuss the results.

Is HALO FDA approved?

Yes, HALO is FDA approved.

Is HALO reimbursed by my insurance company?

The collection of NAF with the HALO system is not yet reimbursed by insurance companies. Contact your doctor about your cost for the HALO test. If you produce fluid during the HALO test, your doctor's office will send this sample to the lab to be evaluated. The charges associated with the lab are covered by most insurance companies.

Can I have a HALO if I have breast implants?

It depends on the type of implant. If your incision is not around the entire nipple, you may have the HALO.

Can I have a HALO if I've had a breast reduction?

No. Breast reduction surgery blocks the milk ducts where nipple aspirate fluid is found.

Can I have a HALO if I have a nipple ring?

Yes, however you must remove the ring(s).

Is color of Nipple Aspirate (NAF) important?

No. NAF can be any color.